

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

**Nextern Inc.**  
**dba Nextern Innovation, LLC**  
1185 Birch Lake Boulevard North  
White Bear Lake  
Minnesota  
55110  
USA

Holds Certificate Number: FM 677060

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, Development, Contract Manufacturing, Testing, Sterilization and Warehousing of integrated system (electro- mechanical) pneumatic and pulse generating medical equipment and therapy delivery (electro-mechanical and mechanical only) hand steerable body insertion devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2017-01-27

Latest Revision Date: 2023-08-08

Effective Date: 2023-08-25

Expiry Date: 2026-08-24

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Certificate No: FM 677060

Location	Registered Activities
Nextern Inc. dba Nextern Innovation, LLC 1185 Birch Lake Boulevard North White Bear Lake Minnesota 55110 USA	Design, Development, Manufacturing, Testing, Sterilization and Warehousing of OEM integrated system (electro-mechanical) pneumatic and pulse generating medical equipment and therapy delivery (electro-mechanical and mechanical only) hand steerable body insertion devices.
Nextern Inc. dba Nextern Innovation, LLC 6500 Wedgwood Road Maple Grove Minnesota 55311 USA	Design, Development, Contract Manufacturing, Testing, Sterilization and Warehousing of integrated system (electro-mechanical) pneumatic and pulse generating medical equipment and therapy delivery (electro-mechanical and mechanical only) hand steerable body insertion devices.



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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

Issuing Body: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

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